Exhibit 10

U.S. Department of Justice

John F. Walsh
United States Attorney
District of Colorado

1225 17th Street, Suite 700
Denver, CO 80202

Telephone: 303-454-0109
Fax: 303-454-0404

August 13, 2014

Via Federal Express

Geoffrey Hobart, Esq.
Covington & Burling LLP
1201 Pennsylvania Avenue, N.W.
Washington, D.C. 20004

Re: Possible Civil Action Against McKesson Corporation for Violations of the Controlled Substances Act

Dear Mr. Hobart:

The United States Attorney's Office for the District of Colorado, in conjunction with the Drug Enforcement Administration ("DEA"), is investigating whether the McKesson Corporation's Aurora Distribution Center ("McKesson-Aurora"),[1] located at 14500 East 39th Avenue, Aurora, Colorado 80011, violated the Comprehensive Drug Abuse Prevention Control Act of 1970, 21 U.S.C. §§ 801 *et seq.*, ("CSA" or "Controlled Substances Act").

I. Introduction.

Colorado is grappling with an epidemic of prescription drug abuse and has the dubious distinction of having the second highest rate of prescription drug painkiller abuse in the United States. *See* Attachment 1, "State Estimates of Nonmedical Use of Prescription Pain Relievers," National Survey on Drug Use and Health (January 8, 2013). More than 255,000 Coloradans now misuse prescription drugs. *See* Attachment 2, "Colorado Plan to Reduce Prescription Drug Abuse," Office of Governor John Hickenlooper (September 2013), at 2. In recent years, prescriptions for certain

[1] Throughout this letter, "McKesson" will refer to McKesson Corporation, whereas "McKesson-Aurora" will refer to McKesson's distribution center located 14500 East 39th Avenue, Aurora, Colorado 80011.

prescription drugs like oxycodone have soared. *See* Attachment 3. And so have deaths due to use of these drugs. Deaths in Colorado related to opioid analgesics have quadrupled in recent years. *Id.* Recently, Colorado hospitals have also seen a dramatic increase in the numbers of babies born physically dependent upon drugs, including prescription drugs. *See* http://www.cpr.org/news/story/hooked-birth-6-percent-colorado-newborns-may-suffer-drug-withdrawal. The number of babies suffering from drug dependency at birth has doubled in the past five years at Children's Hospital Colorado located in Colorado Springs. *Id.* Similarly, Parkview Medical Center in Pueblo, Colorado reported 18 babies born dependent on drugs in 2013, up from only 2 babies in 2009. *Id.*

The DEA has a mandate to prevent illegal diversion of controlled substances. One of the important tools that the DEA relies on in accomplishing this task is suspicious-order reporting from DEA registrants. The CSA requires distributors like McKesson-Aurora to report suspicious orders to the DEA in order to assist the DEA with its law enforcement and regulatory efforts. *See* 21 C.F.R. § 1301.74(b).

This regulatory requirement to report to suspicious orders is not meaningless box-checking. Suspicious-order reporting serves a concrete, public-safety goal. Distributors are on the front lines and, thus, in a unique position to promptly advise the DEA when they receive an order that is unusual, deviates from a normal pattern, or is otherwise suspicious or inappropriate. If the distributor does not alert the DEA of such orders, then the DEA cannot take the necessary law enforcement steps to investigate the orders and prevent diversion. In this manner, distributors like McKesson-Aurora play a vital role in preventing diversion and saving lives.

Our investigation has determined that McKesson-Aurora failed to comply with its legal obligation to report suspicious orders. Although McKesson-Aurora paid lip service to a compliance program designed to prevent illegal diversion of controlled substances, this distribution center actually did very little to discover suspicious orders and report those orders to the DEA. Time and time again, McKesson-Aurora received information about orders that were unusual or exceeded even generous thresholds, but failed to report those orders. Many of the compliance controls in place to detect suspicious orders — such as site visits to pharmacies and pharmacy questionnaires — were either ignored or were treated by McKesson-Aurora personnel as perfunctory. McKesson-Aurora failed to take steps that could have potentially halted distribution to pharmacies of large amounts of controlled substances that were being dispensed for other than a legitimate medical purpose.

Our investigation has revealed that McKesson-Aurora repeatedly looked the other way, even when McKesson-Aurora was faced with very troubling evidence indicating potential diversion. It performed very little due diligence to determine why some of its independent pharmacy customers were ordering large quantities of controlled substances.

Even when McKesson-Aurora received information clearly showing suspicious orders by its pharmacy customers, it often failed to report even those obviously suspicious orders to the DEA. Instead, when McKesson-Aurora received a suspicious order from one of its pharmacy customers, the distribution center manipulated its internal control systems in various ways to avoid having to report that order.

The result was that readily identifiable orders and ordering patterns that were obvious signs of diversion occurring at McKesson-Aurora customer pharmacies went unreviewed and unreported. In this manner, McKesson-Aurora's desire for increased sales drove its compliance efforts.

McKesson-Aurora's failure to report suspicious orders to the DEA has had tangible and tragic consequences. At least nine overdose deaths in Colorado can be traced to purchases made at pharmacies that were purchasing unusually high quantities of oxycodone and hydrocodone from McKesson-Aurora. At least two drug-trafficking organizations were operating out of McKesson-Aurora-supplied pharmacies and diverting prescription drugs for sales on the street, but McKesson-Aurora never once reported those pharmacies' blatant pattern of suspicious ordering to the DEA.

II. Background on McKesson.

McKesson Corporation ("McKesson") is an industry leader in a profitable and growing pharmaceutical distribution market. It is the 15th largest company in the United States. It is one of three companies that control a combined 90% of the pharmaceutical distribution market in the United States. According to McKesson's securities filings, McKesson had a total of $122 billion in revenues ($105 billion of which is attributable to U.S. pharmaceutical distribution and related services) and $1.338 billion in profits in the 2013 Fiscal Year. These numbers have grown over time. In 2009, McKesson had a total of $106 billion in revenues ($96 billion of which was attributable to U.S. pharmaceutical distribution and related services) and $823 million in profits.

McKesson's distribution of controlled substances is a significant component of its overall business. McKesson owns and operates 28 facilities nationwide that are registered with DEA as distributors. These distribution centers service approximately 25,000 pharmacies daily and process 1.2 million order lines per night.

McKesson-Aurora is one of the 28 distribution centers and is registered with DEA as a distributor in controlled substances, Schedules II-V, pursuant to DEA Certificate of Registration PM0018425. McKesson-Aurora has approximately 530 customers. In 2011, McKesson-Aurora was recognized with the "Distribution Center of the Year" award.

III. McKesson-Aurora Had a Legal Obligation to Report Suspicious Orders to the DEA.

A. McKesson Is Required by the CSA to Report Suspicious Orders.

DEA registrants such as McKesson-Aurora are required to "maintain[] effective controls against diversion of particular controlled substances into other than legitimate medical, scientific, and industrial channels." 21 U.S.C. § 823(b)(1). McKesson-Aurora is also required to "design and operate a system to disclose to the registrant suspicious orders of controlled substances." 21 C.F.R. § 1301.74(b).

"Suspicious orders" is a broad phrase that includes, for example, "orders of unusual size, orders deviating substantially from a normal pattern, and orders of unusual frequency." *Id.* The DEA has also explained to registrants that these criteria are not all-inclusive, and that any of these factors render an order suspicious. *See* Attachment 4, Letter to Registrants from DEA Deputy Assistant Administrator Joseph Rannazzisi dated December 20, 2007 (explaining that these criteria are disjunctive and are not all inclusive). The DEA explained that, in practice:

- An order that deviates substantially from a normal pattern should be reported as suspicious, regardless of the size of the order. *Id.* at 1. The determination of whether an order deviates from the normal pattern depends not only on the ordering patterns of a particular pharmacy, but also on the registrant's entire customer base and relevant segment of the industry. *Id.* at 2.

- The size of an order, alone, can be enough to trigger the registrant's responsibility to report the order as suspicious. *Id.* at 1-2.

- It may not be enough for a registrant to establish a system that identifies an order as suspicious only if the total amount of a controlled substance ordered during one month exceeds the amount ordered the previous month by a certain percentage. *Id.* at 2. If the pharmacy placed unusually high orders from the beginning of its relationship with a distributor, this system would not detect those orders as suspicious. *Id.*

A registrant's responsibility does not merely stop with the reporting of the suspicious order to the DEA. In addition, "[r]egistrants must conduct an independent analysis of suspicious orders prior to completing a sale to determine whether the controlled substances are likely to be diverted from legitimate channels." *Id.* at 1. That means that registrants that routinely fill these orders — without first determining whether the order is likely to be diverted — are failing to maintain effective controls against diversion.

B. McKesson-Aurora Undertook Additional Obligations in the 2008 Settlement Agreement and the 2008 Memorandum of Agreement.

In 2008, McKesson entered into a Settlement Agreement with the Department of Justice and a Memorandum of Agreement ("MOA") with the DEA related to, among other things, McKesson's failure to report suspicious orders of controlled substances to the DEA, as required by 21 C.F.R. § 1301.74(b). The settlement involved CSA violations by McKesson from multiple districts around the country, including the District of Colorado. The Colorado violations resolved by the settlement related to McKesson-Aurora's failure to report the purchases of large quantities of hydrocodone by three Colorado pharmacies: Brighton Pharmacy in Brighton; Western States Pharmacy in Brighton; and St. Vrain's Pharmacy in Lyons. *See* Attachment 5, Settlement Agreement, at ¶ 8D. Under the terms of the April 30, 2008 Settlement Agreement, McKesson agreed to pay the United States $13,250,000 in exchange for a release from civil liability under 21 U.S.C. § 842(c)(1). *See id.* at ¶¶ 13-14.

On May 2, 2008, McKesson also entered into the MOA with the DEA. *See* Attachment 6, Memorandum of Agreement. McKesson-Aurora was specifically mentioned in Appendix A of the MOA. Under the terms of the MOA, McKesson agreed to comply with its obligations under federal law in the future:

- McKesson agreed to maintain a compliance program designed to detect and prevent diversion, including a program to review orders for controlled substances. *Id.* at ¶ II.1.a.

- McKesson agreed that if a controlled substance order exceeded "established thresholds and criteria," those orders would be reviewed by a McKesson employee "trained to detect suspicious orders." *Id.*

- McKesson agreed that if it discovered a suspicious order, it would report the order directly to DEA Headquarters (rather than the local DEA field office, as required by the federal regulations). *Id.* at ¶ II.1.c.

In sum, after the MOA, McKesson-Aurora had a regulatory obligation under 21 C.F.R. § 1301.74(b) stemming from its status as a DEA registrant, as well as a contractual obligation stemming from the 2008 Settlement Agreement and MOA, to report suspicious orders of controlled substances to the DEA. McKesson-Aurora — of all drug distributors registered as DEA registrants — should have been particularly attuned to its obligation to report suspicious orders.

IV. McKesson Further Agreed to a Controlled Substance Monitoring Program.

A. The CSMP Recognizes McKesson's Duty to Detect Suspicious Orders.

As a direct result of the 2008 settlement, McKesson developed a program called the Controlled Substance Monitoring Program ("CSMP"), in which McKesson recognizes that it has a duty to monitor its sales of all controlled substances so that it can report suspicious orders to the DEA. According to McKesson's Operations Manual, the purpose of its CSMP is to

- "Proactively review the customer's order and purchases for all controlled substances in order to detect and prevent diversion
- Set and maintain customers' thresholds for all controlled substances
- Make informed decisions based upon established threshold information
- Build a documented business case to substantiate the volume of controlled substances purchased by McKesson customers
- Report to the DEA those orders / purchases / customers designated as 'suspicious'."

See Attachment 7, CSMP Operations Manual dated September 16, 2008.[2]

B. The CSMP was Intended to Set, and Maintain, Thresholds.

As noted, the CSMP explains that one of its purposes is to "[s]et and maintain customers' thresholds." These thresholds are the maximum dosage units of a particular drug (assigned a "base code" by the DEA) that each customer is allowed to purchase from McKesson in any given month. In other words, one of the stated goals of the CSMP is to set the maximum monthly amount of a given controlled substance that a pharmacy customer can purchase, and then use that threshold to detect diversion by monitoring when the customer exceeds the threshold.

Under the CSMP, once a customer reaches its monthly maximum threshold amount, McKesson is supposed to "block" all subsequent orders for that item for the remainder of the month. The following month, the customer's sales history is "refreshed" and the sales for that item are set back to zero, allowing the customer to once again purchase up to the threshold amount.

[2] For the purposes of this letter, the description of the CSMP refers to its application to independent retail pharmacies.

At the outset, McKesson is supposed to establish thresholds based upon each individual pharmacy's past ordering patterns. For existing customers, McKesson "originally set up the thresholds in 2008 based on an existing customer's 12 month usage number on a particular basecode" by "[taking] the highest month of that year and add[ing] 10%" — a "buffer [that] allowed for unusual fluctuations from month to month." *See* Attachment 8, MCK_00165197. For new customers, the CSMP requires McKesson to establish thresholds by having the new customer complete a questionnaire and provide three months of sales history. *See* Attachment 7, at Section 1.2.2. McKesson relies on a "Family Matrix" that it created to establish minimum thresholds for each drug code based upon the customer type (retail national account, hospital, independent retail pharmacy, etc.) and purchasing volume. Once the customer type and purchasing volume are determined from the customer questionnaire, McKesson is supposed to apply the Family Matrix to establish initial thresholds for new customers.

The CSMP also sets forth the method by which a customer's threshold for a particular drug code can be increased. *Id.* at Section 1.3. A McKesson representative, typically sales personnel, will complete a threshold change request ("TCR") form, justifying why the pharmacy needs to increase the threshold for a given month. The TCR form documents why the pharmacy needs an increase (*i.e.*, increase in business, emergency request, etc.). Threshold increases can be temporary for that month or permanent. Threshold changes must be approved by the Regional Director of Regulatory Affairs ("DRA"). For McKesson-Aurora, the Regional DRA is Tom McDonald.

C. Warning Reports and Omit Reports.

The CSMP states that McKesson is to provide customers with two reports as customers approach their monthly threshold for a particular drug: a "warning report" as the customer approaches the threshold, and an "omit report" if the threshold is reached.

A threshold "warning report" is supposed to issue when a pharmacy customer reaches 90 percent of its threshold for a particular drug. The DRA is supposed to notify the McKesson-Aurora distribution center management that the customer is at 90 percent. *Id.* at Section 2.1. The distribution center management can then contact the customer and discuss increasing threshold levels, at their discretion. An invoice is also supposed to be generated to alert the customer that it has reached 90 percent of its threshold.

A threshold "omit report" — sometimes referred to as a threshold "incursion report"[3] — is issued once a pharmacy customer reaches its monthly maximum threshold amount. At that point, all subsequent orders for that item are supposed to be blocked. *Id.*

[3] In at least one instance, the CSMP refers to this as "Threshold Excursion" rather than "Threshold Incursion." *See* Attachment 7, at Section 2.2.

at Section 2.2. The only way for a customer's order to become "unblocked" is if (1) the threshold is temporarily changed, (2) the threshold is permanently changed, (3) the customer returns some product such that the customer falls below the threshold, or (4) the sales history becomes refreshed at the beginning of a new month. *Id.*

D. The CSMP Recognizes McKesson's Duty to "Know Their Customer."

The CSMP dictates that all McKesson distribution centers, including McKesson-Aurora, must "know their customer." *Id.* at 1. According to the CSMP, "[t]his means understanding the customer's business, *why* they purchase as well as how much they purchase. Factors such as type of business, internet activities, type and quantity of products purchased should be considered when evaluating a customer." *Id.* (emphasis in original). The CSMP sets forth several ways in which McKesson can garner an understanding of its customers' businesses:

- Pharmacy Questionnaires: The CSMP requires the completion of detailed Pharmacy Questionnaires for new and existing customers, on a periodic basis. *Id.* at Section 3.2.

- Site Visits: The CSMP also states that McKesson is to conduct physical site visits to its customers' stores. On these site visits, McKesson personnel are to observe, among other things, whether the "customer's business [is] in a site that appears consistent with their business type and volume?" The CSMP expressly states that personnel should consider the population and other businesses located in the surrounding area. *Id.* at Section 3.2.2.7.

- Customer Interviews: McKesson's CSMP also has a separate provision for a "Customer Interview." The interview is supposed to occur at the pharmacy site in order to "view the pharmacy operations." Further, the interview is supposed to be scheduled as soon as possible because "DEA expects McKesson's responses to suspicious activities to be prompt and timely." *Id.* at Section 3.3.

The CSMP notes that McKesson can also conduct further "due diligence" through an inquiry with the DEA or the Board of Pharmacy, an internet search, or extensive background search via corporate security.

E. The CSMP Requires Higher-Level Review of Potentially Suspicious Orders.

The CSMP provides a system for higher-level management review of potentially suspicious orders. If a customer reaches its threshold and receives an omit report for a

particular controlled substance, the review may involve local, regional, or national management:

- Level 1 Review: A Level 1 review is ***required*** for all threshold incursions. McKesson's local distribution center management is supposed to contact the customer upon the incursion and advise the customer that a controlled substance has been omitted because the threshold has been met. Management will then undertake to determine why the incursion has occurred, inquiring as to whether the customer has any new business and possibly evaluating the customer's last three months of purchases. Local distribution center management can request a temporary or permanent threshold change, but if the evaluation of the order is inconclusive, then McKesson is supposed to escalate the matter to a Level 2 review. *Id.* at Section 2.2.2.

- Level 2 Review: The local distribution center management can forward all information from the Level 1 review to the Regional DRA. The DRA will then discuss the review process with the distribution center management and determine if the sales were appropriate. There are three possible outcomes from a Level 2 review: (1) McKesson can continue to block the controlled substance until the following month when the sales history is refreshed, (2) McKesson can request a temporary or permanent threshold change, or (3) the DRA can escalate the matter to a Level 3 review. *Id.* at Section 2.2.3.

- Level 3 Review: If the Level 1 and Level 2 reviews conclude that the order is potentially suspicious, a Level 3 review is supposed to be conducted by senior national McKesson management. At this point, ***all*** controlled substance sales to that customer are supposed to be blocked. McKesson is then supposed to report the customer and transaction to DEA headquarters as "suspicious." *Id.* at Section 2.2.4.

The CSMP further mandates that McKesson take action if it thinks that a customer is engaging in inappropriate activity or questionable practices, even if the order amounts did not reach any thresholds. According to the CSMP Operations Manual, "[i]f at any time McKesson (this includes sales, operations, regulatory) suspects any wrong doing, inappropriate activity and/or questionable practices, McKesson has the responsibility to react. This requirement is regardless of customer type, size, tenure, revenue, purchase quantities or threshold amounts." *Id.* at Section 4. The CSMP also gives the regulatory department the ability to block a controlled substance to a customer or suspend a shipment of controlled substances to any customer at any time. *Id.* at Sections 2.3 and 4.

V. McKesson-Aurora's Failure to Report Suspicious Orders to the DEA.

A. Between 2008 and 2013, McKesson-Aurora Submitted Only 16 Suspicious Order Reports.

After specifically agreeing to come into compliance with 21 C.F.R. § 1301.74(b) under the terms of the 2008 MOA, McKesson-Aurora submitted almost no suspicious order reports ("SORs") to the DEA from 2008 through 2013, as set forth below:

- From May 2, 2008, through March 25, 2012, McKesson-Aurora did not submit any SORs to the DEA.
- On March 26, 2012, McKesson-Aurora submitted 16 SORs to DEA Headquarters. All 16 SORs were submitted in a single batch and they all related to one pharmacy: Dales's Pharmacy in Fort Lupton, Colorado, DEA No. FD1023097. All 16 SORs were for orders that had been placed between January 20, 2012, and March 13, 2012, with no explanation for the untimely delay in submitting some of these reports to the DEA.
- From March 27, 2012, through June 23, 2013, McKesson-Aurora did not submit any SORs to the DEA.
- On March 12, 2013, the United States executed its Administrative Inspection Warrant and simultaneously served McKesson-Aurora with a subpoena for documents.
- From June 24, 2013, through November 30, 2013, McKesson-Aurora submitted approximately 2,447 SORs to the DEA.

Thus, in the five years before McKesson-Aurora knew that it was being investigated but was subject to the MOA, it reported a total of 16 orders as suspicious, in one batch, occurring in one quarter, at one pharmacy that McKesson-Aurora had recently terminated. To put that figure in its proper perspective, McKesson reported to the DEA ARCOS system that it received, processed, and filled a total of 1.6 million orders for controlled substances during that same time frame. This disparity, alone, demonstrates that McKesson Aurora was operating for years without any functional "system to disclose . . . suspicious orders of controlled substances" to be reported to the DEA. *See* 21 CFR 1301.74(b).

It was not until after the United States served a warrant and subpoena — and made it known that the United States was actively investigating whether McKesson-Aurora had complied with its regulatory and MOA obligations to report suspicious orders — that McKesson-Aurora suddenly began reporting suspicious orders to the DEA. This

very act of reporting almost 2,500 SORs in a five-month period in 2013 is strong evidence that McKesson-Aurora knew it should have been reporting suspicious orders all along.

B. McKesson-Aurora's Desire for Increased Sales Overrode Its Obligations to Report Suspicious Orders.

Our investigation has revealed a disturbing pattern: McKesson-Aurora's desire for increased sales and retaining its customers overrode its obligations to report suspicious orders. We have identified this trend across several different areas.

1. *McKesson-Aurora Manipulated and Circumvented Thresholds.*

Thresholds were supposed to be the linchpin of McKesson's compliance program. But McKesson-Aurora manipulated customers' threshold levels, in numerous ways, to avoid rigorous internal review.

First, McKesson-Aurora set its initial thresholds for its pharmacy customers very high. McKesson-Aurora's review process was not even triggered until an individual pharmacy sold more than 10% of that pharmacy's average volume from a 12-month period from 2007-2008 — a year in which McKesson had settled claims because diversion was flourishing in McKesson-supplied pharmacies.

Moreover, McKesson's CSMP did not even attempt to detect if diversion was already occurring back in 2008 when the initial thresholds were set. Thus, to the extent diversion was already occurring, such diversion could continue, as long as the customer did not stray too far from those initial thresholds.

In some cases, McKesson-Aurora set some thresholds so high at the outset that the pharmacy customer would never exceed it, and thus, never trigger any review as to whether an order was indeed suspicious. This appears to have happened with hydrocodone purchases more than oxycodone purchases. Take, for example, PDC Pharmacy Inc. dba Goose Creek Pharmacy. Our analysis indicates that McKesson-Aurora set Goose Creek's hydrocodone monthly threshold at 8,000 dosage units, which was about 5,000 dosage units higher than Goose Creek's typical ordering pattern of 1,000 to 3,000 dosage units. *See* Attachment 9, PDC Pharmacy (hydrocodone). In another example, on June 10, 2009, the owner of the Lajara Pharmaceutical Center reported that he sold 6,500 dosage units of hydrocodone products per month. Yet McKesson-Aurora set Lajara Pharmaceutical Center's hydrocodone threshold at 13,000 dosage units a month — double the amount that this pharmacy estimated it would be purchasing. By setting the hydrocodone thresholds well above the pharmacy's typical monthly ordering quantity, McKesson-Aurora avoided its obligation to keep an eye on whether sales to these pharmacies were in fact deviating from the normal pattern.